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|----------------------------|-------------|----------------------|------------------------|------------------|
| APPLICATION NO.            | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |
| 10/553,630                 | 08/21/2006  | Carin Widerstrom     | 15041.0010USWO         | 6047             |
| 23552                      | 7590        | 12/08/2009           | EXAMINER               |                  |
| MERCHANT & GOULD PC        |             |                      | JACOBSON, MICHELE LYNN |                  |
| P.O. BOX 2903              |             |                      | ART UNIT               | PAPER NUMBER     |
| MINNEAPOLIS, MN 55402-0903 |             |                      | 1794                   |                  |
| MAIL DATE                  |             | DELIVERY MODE        |                        |                  |
| 12/08/2009                 |             | PAPER                |                        |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |
|------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/553,630 | <b>Applicant(s)</b><br>WIDERSTROM, CARIN |
|                              | <b>Examiner</b><br>MICHELE JACOBSON  | <b>Art Unit</b><br>1794                  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 19 August 2009.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-25 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Examiner Notes***

1. Any objections and/or rejections made in the previous action, and not repeated below, are hereby withdrawn.

***Election/Restrictions***

2. Newly amended claims 15 and 16 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Article claims 1-14 and 17-25 do not require that the sachet contain a pharmaceutical composition, only that it be capable of performing the intended use of being "for a pharmaceutical composition". Therefore, the article recited in claimed one could be used for a materially different method, such as containing non-pharmaceutical compositions, from that recited in method claims 15 and 16.
3. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for -- prosecution on the merits. Accordingly, claims 15 and 16 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

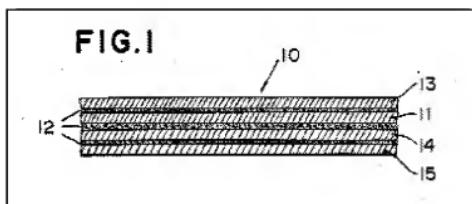
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3-7, 9-14, 17-19 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Asakura et al. U.S. Patent No. 4,360,550 (hereafter referred to as Asakura).

6. Asakura teaches a packaging pouch for packing materials such as medicines comprising a laminate film. (Col. 1, lines 8-13, Fig. 1) The laminate film comprises a base film (11) of paper or aluminum foil. When paper is used the thickness is recited to be in the range between 40-90 g/m<sup>2</sup>. (Col. 3, lines 63-66) When Al foil is used, the thickness is recited to be in the range of between 7 to 30 µm. (Col. 4, lines 5-8)

7. The base layer (11) is recited to be adhered between two HDPE layers, (13) and (14), having a thickness between 10-50 µm. (Col. 4, lines 9-23) A sealant layer (15) comprising low density polyethylene in a thickness between 15 to 120 µm is laminated on one of the HDPE layers. (Col. 5, lines 25-53) In the examples of Asakura, the sealant layer is disclosed to have a thickness of 30 µm. (Col. 6, line 45) Adhesive layers, (12), are disposed between all of the layers of the laminate.



8. Regarding claim 1: Asakura clearly recites a laminate comprising an "outer" paper layer (11) (outer being interpreted to mean that the paper layer is disposed nearer the exterior of the sachet than the bonding layer), a bonding layer (12), a barrier layer (14) and a sealing layer (15).

9. Regarding claims 3-5: Asakura clearly recites that the paper layer has a weight per unit area of 40-90 g/m<sup>2</sup>. The recitation of 40 g/m<sup>2</sup> anticipates points within all of the ranges recited in claims 3-5.

10. Regarding claims 9, 10 and 17-19: Asakura clearly recites that the sealing layer be between 15-120 µm thick which anticipates a data point in the range claimed in claim 9. The sealing layer is recited to comprise an LDPE with a density less than 0.92 g/cm<sup>3</sup>.

When converted for a layer 15 µm thick, the LDPE sealing layer would have a mass per unit area of 13.8 g/m<sup>2</sup>, and a 30 µm thick sealing layer as recited in the examples would have a mass per unit area of 27.6 g/m<sup>2</sup> which anticipates a data point within the ranges claimed in claims 10 and 17-19.

11. Regarding claims 11 and 21-24: The HDPE layer interpreted by the examiner to read on the barrier layer iii) of claim 1 is recited to be between 10-50 µm thick which anticipates a point within the ranges claimed in claims 11 and 21-24.

12. Regarding claims 12-14: Asakura clearly recites that the pouch of the invention is useful for medicines which is interpreted by the examiner to read on the pharmaceutical formulations claimed in claim 12. While there is no disclosure that the pouch disclosed by Asakura is used for mesalazine or a pharmaceutically acceptable salt thereof as presently claimed, applicants attention is drawn to MPEP 2111.02 which

states that "if the body of a claim fully and intrinsically sets forth all the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction". Further, MPEP 2111.02 states that statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the *purpose or intended use results in a structural difference between the claimed invention and the prior art*. Only if such structural difference exists, does the recitation serve to limit the claim. If the prior art structure is capable of performing the intended use, then it meets the claim.

13. It is the examiner's position that the preamble does not state any distinct definition of any of the claimed invention's limitations and further that the purpose or intended use, i.e. packaging mesalazine or a pharmaceutically acceptable salt thereof, recited in the present claims does not result in a structural difference between the presently claimed invention and the prior art pouch disclosed by Asakura and further that the prior art structure which is a pouch identical to that set forth in the present claims is capable of performing the recited purpose or intended use. Therefore, the invention of Asakura reads on the limitations of claims 13 and 14.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 2, 6-8, 20 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asakura et al. U.S. Patent No. 4,360,550 (hereafter referred to as Asakura).

16. Asakura teaches what has been recited above, but is silent regarding using an Al foil layer and paper layer simultaneously and the identity of the bonding layer, the weight per unit are of the bonding layer, a weight per unit are of the sealing layer between 30-40 g/m<sup>2</sup> or 35 g/m<sup>2</sup> and a thickness of the barrier layer of 12 µm.

17. Regarding claim 2: It is well known in the polymer packaging arts that Al foil layers provide excellent barrier properties to laminates. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have included an Al foil layer in addition to the paper layer recited by Asakura to produce a laminate with good dimensional stability and excellent barrier properties. Furthermore, the utility of polyethylene as a bonding layer between layers of a laminate is also universally known. Although Asakura is silent regarding the identity of the bonding layer, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized polyethylene for such a layer. Such a laminate comprising a paper layer, an Al foil layer, a polyethylene bonding layer and an LDPE sealing layer would have been the same as the laminate claimed in claim 2.

18. Regarding claims 6-8: It would have been obvious to one having ordinary skill in the art at the time the invention was made to have optimized the result effective variable

of thickness of the bonding layer recited by Asakura in order to provide the best adhesion and strength to the laminate while minimizing the amount of material necessary to achieve an acceptable amount of strength and adhesion. Such routine optimization would have produced a bonding layer with a weight per unit area (a value directly dependent on thickness) as recited in claims 6-8.

19. Regarding claim 20: In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) It would have been obvious to one having ordinary skill in the art at the time the invention was made to have optimized the result effective variable of thickness of the sealing layer recited by Asakura in order to provide the best adhesion and strength to the laminate while minimizing the amount of material necessary to achieve an acceptable amount of strength and adhesion. Such routine optimization would have produced a sealing layer with a weight per unit area (a value directly dependent on thickness) as recited in claim 20.

20. Regarding claim 25: In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) It would have been obvious to one having ordinary skill in the art at the time the invention was made to have optimized the result effective variable of thickness of the barrier layer recited by Asakura in order to provide the most desirable barrier properties to the laminate while minimizing the amount of material

necessary to achieve an acceptable barrier property. Such routine optimization would have produced a barrier layer with a thickness as recited in claim 25.

***Response to Arguments***

21. Applicant's arguments filed 8/19/09 have been fully considered but they are not persuasive.
22. Applicant asserts on page 7 of the remarks that Asakura does not disclose the layers recited in claim 1 in the same order as instantly claimed. However, claim 1 only recites a generic bonding layer and a generic barrier layer, both of which are disposed in the same order as claimed in the laminate of Asakura as enumerated above.

Therefore, applicant's arguments are not found persuasive.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE JACOBSON whose telephone number is (571)272-8905. The examiner can normally be reached on Monday-Thursday 8:30 AM-7 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571)272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele L. Jacobson  
Examiner /M. J./  
Art Unit 1794

/Rena L. Dye/  
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